UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PharmacyChecker.com LLC, Plaintiff, v. National Association of Boards of Pharmacy, Alliance for Safe Online Pharmacies, Center for Safe Internet Pharmacies Ltd., and Partnership for Safe Medicines, Inc., Defendants.	Civil Action No.: 7:19-cv-07577-KMK

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF BENJAMIN ENGLAND, ESQ.

Table of Contents

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTRODUCTION

Plaintiff[1] presents no authority supporting the extraordinary proposition that the Court should admit the legal conclusions of an expert that are directly contradicted by relevant law. Despite arguing in opposition to Defendants' *Daubert* motion that England is not seeking to testify about the ultimate legal issues, Plaintiff relies nearly exclusively on England's testimony about the laws and regulations governing prescription drug importation to argue that such importation is lawful in opposition to Defendants' summary judgment motion. *See* ECF No. 269 at 21-26. Plaintiff thus apparently seeks to have England determine the legal questions at issue in this case, thereby supplanting the role of the Court.

Plaintiff mischaracterizes England's testimony as a replacement for legal precedent to support its faulty legal analysis. But, in seeking to defend England's inaccurate and speculative opinions from exclusion, Plaintiff spends much of its opposition defending different opinions than those that England actually proffers. Plaintiff changes the language of England's second opinion, which originally stated that prescription drugs that comply with FDA's approval requirements except for labeling or packaging differences "may be imported under FDA's drug labeling exemptions," to "may be imported legally." *Compare* Ex. 3 at 5, *with* ECF No. 268 at 4. England's third opinion describes the PIP as "guidance to consumers explaining when FDA would *permit* the importation of drugs *that might otherwise be refused admission,*" while Plaintiff now asserts that he opined the "PIP explains to consumers when importation of prescription drugs is *permissible under the relevant laws*." *Compare* Ex. 3 at 5 (emphasis added), *with* ECF No. 268 at 4 (emphasis added). The reality is that England's actual opinions

[1] All capitalized terms and abbreviations have the same meanings as defined in Defendants' Opening Brief ECF No. 260.

and testimony contradict PCC's summary, as England repeatedly makes the distinction between discretion and illegality, stating that "the PIP is not law." Ex. 2 at 303:5-11. Plaintiff leaves out of England's first opinion that "FDA lacks the power to prevent such importations." *Compare* Ex. 3 at 5, *with* ECF No. 268 at 4. This opinion directly goes to the heart of the enforcement discretion England discussed throughout his testimony, which is very different from legality. Finally, Plaintiff removes from England's fourth opinion that Plaintiff "does not buy, sell, distribute, dispense, or process orders for drugs," and adds that his opinion is based upon Plaintiff's policies "as stated on its website[.]" *Compare* Ex. 3 at 5, *with* ECF No. 268 at 4. Plaintiff reframes this opinion to highlight the only piece of evidence that England acknowledged reviewing when forming his opinion.

England's opinions, whether as stated in his Report or otherwise, should be excluded either as inaccurate legal conclusions or as unfounded speculation. Beyond his incorrect legal opinions, England's opinions about the design of Plaintiff's accreditation program and the exercise of FDA enforcement discretion are both unreliable speculation that will not assist the finder of fact.

II. ARGUMENT

A. The Court Should Exclude England's Incorrect Legal Opinions.

The bulk of England's Report is made up of impermissible legal conclusions that should be excluded.[2] Each of England's first three opinions misstates the federal laws, regulations, and guidance governing prescription drug importation as laid out by the Eighth Circuit in *In re*

[2] Although Defendants did not challenge England's qualifications as an expert, Defendants did not "concede that England is an expert on regulation and policy of U.S. drug importation," nor "that his expertise and career knowledge is relevant and helpful[.]" ECF No. 268 at 1. In fact, Defendants expressly argued that certain of his opinions were speculation that would not assist the trier of fact.

Canadian Import Litigation, 470 F.3d 785 (8th Cir. 2006), cited with approval in *Biocad JSC v. Hoffmann-La Roche*, 942 F.3d 88, 104 (2d Cir. 2019) (Katzmann, J., concurring). Unsurprisingly, none of the authority Plaintiff cites allows admission of inaccurate legal opinions. Further, although an expert may describe the regulatory scheme in order to provide background to the finder of fact, an expert may not invade the province of the Court by determining a legal question at issue in the case.

1. England Inaccurately and Improperly Interprets Federal Law and Regulations Governing Prescription Drug Importation.

The Court should exclude England's opinions about the legality of prescription drug importation because they are inaccurate. Plaintiff argues in opposition to Defendants' motion that "[t]he 'correctness' of an expert's testimony is a ***factual*** inquiry that should be left to the jury" rather than a basis for exclusion. ECF No. 268 at 6 (emphasis added). Although that may be correct when an expert opines as to factual matters, it is not the case here where England offers opinions of ***law***. *Id.* at 12 (describing "England's first three opinions" as "importation of prescription drugs is not illegal so long as certain conditions are met.") None of the cases Plaintiff cites support the proposition that the Court should disregard substantive correctness in determining whether to exclude an expert opinion that concerns the very legal opinions at issue in the case. *See, e.g.*, *In re Pfizer Inc. Sec. Litig.*, 819 F.3d 642, 648 (2d Cir. 2016) (testimony about "the extent to which[] Pfizer's stock price changed"); *Smith v. Ford Motor Co.*, 215 F.3d 713, 716-17 (7th Cir. 2000) (testimony of two engineers); *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 467-68 (S.D.N.Y. 2018) (general statement of *Daubert* principles).

More apt to the question at hand, then, are the cases Defendants originally cited and Plaintiff repeats in its opposition. *See generally* ECF No. 268 at 14. Each of these cases address

the exclusion of legal testimony that is inaccurate. For example, Plaintiff points out that *Mars, Inc. v. TruRx LLC* excluded "expert legal opinions that directly contradicted controlling Federal Circuit precedent." *Id.* (citing No. 6:13-cv-526-RWS-KNM, 2016 U.S. Dist. LEXIS 121889, at *7-8 (E.D. Tex. Apr. 18, 2016)). So, too, should this Court exclude England's opinions that directly contradict applicable law.

In seeking to prop up support for the admission of incorrect legal opinions, Plaintiff argues that *Loeffel Steel Prods., Inc. v. Delta Brands, Inc.* is inapplicable because the expert's opinion in that case, "unlike here, had no support anywhere." ECF No. 268 at 14. But, in fact, that is exactly the situation here. Nowhere in its opposition does Plaintiff point to a single case from any Circuit supporting England's opinion "that personal importation of prescription drugs is legal in various circumstances[.]" *Id.* Instead, in arguing why England's legal opinions are correct, Plaintiff quotes at length from England's own deposition testimony. *See id.* at 15-18. Plaintiff also quotes England in support of its erroneous contention that 21 U.S.C. § 384(j) is effective and that the PIP is law (and not a policy setting forth when the FDA will exercise its enforcement discretion). *See id.* at 18. And, England has no support for his interpretation of the PIP, which on its face is not applicable to the personal importation of drugs that are commercially available in the U.S. This lack of legal support is hardly surprising given that England testified he did not do any legal research to support his opinions. Ex. 2 at 107:5-9, 109:4-110:4.

Defendants, on the other hand, demonstrated that England's legal opinions are directly contradicted in *Canadian Import*. *See* 470 F.3d 785, 789-92. In response, Plaintiff makes a series of baseless attacks on the Eighth Circuit's decision. Plaintiff criticizes the Eighth Circuit for performing "no discovery or investigation regarding what the FDA meant" in holding that

Congress created a "closed" system for prescription drugs. ECF No. 268 at 17. But Plaintiff offers no explanation why discovery would be needed on a legal question of statutory interpretation. Plaintiff next argues that this was a "passing comment" made in *dicta*. *Id.* at 15. In fact, the conclusion that Congress "creat[ed] [a] comprehensive regulatory system" underlies the ultimate holding that "Congress has effectively precluded importation of these drugs" from foreign countries. 470 F.3d at 790-91. As a last ditch attempt, Plaintiff argues that the Eighth Circuit's analysis "is not correct," citing its opposition to Defendants' summary judgment motion, ECF No. 268 at 17, which, in turn, repeatedly relies on England's Report and deposition testimony for legal conclusions. *See* ECF No. 269 at 23-24. Plaintiff thus relies on England's testimony to defend its own accuracy on an issue of pure law and ultimately argues that the Court should believe England's interpretation of federal laws and regulations over the Eighth Circuit's and this Court's own reading of the applicable law. The Court should reject Plaintiff's request to admit these erroneous legal opinions.

2. It is the Role of the Court, not an Expert, to Determine the Law.

Although in some instances expert regulatory testimony may be admissible, England's opinions are not because they invade the province of the Court. The undisputed evidence establishes that Plaintiff provides a platform for consumers in the United States to personally import prescription drugs. *See, e.g.*, DX 40, PCC_0143288 ([redacted]); DX 41, Cooperman Dep. Ex. 12 (recommending patients "look[] internationally" if they "can't afford the brand locally"). A dispositive issue here is whether personal drug importation is illegal. Such questions of law are the province of the Court.

England's first three opinions directly address a dispositive issue. While Plaintiff quotes extensively from Judge Scheindlin's decision in *In re Methyl Tertiary Butyl Ether Products Liability Litigation v. Exxon Mobil Corp.* to argue that expert testimony involving legal conclusions is admissible, the passages Plaintiff omits show why England's testimony is inadmissible: "[T]he Federal Rules of Evidence still permit a court 'to exclude opinions phrased in terms of inadequately explored legal criteria.' . . . In other words, 'although an expert may opine on an issue of *fact* within the jury's province, [s]he may not give testimony stating ultimate legal conclusions based on those facts.'" No. 00 CIV 1898, 2009 U.S. Dist. LEXIS 63563, at *28-29 (S.D.N.Y. July 21, 2009) (citing Fed. R. Evid. 704 1972 Advisory Committee Note) (emphasis added); *see also id* at n. 155 (describing that Second Circuit jurisprudence, unlike some other courts, establishes that legal conclusions are inadmissible).[3] Any question about whether England proffers dispositive legal conclusions or operative legal standards is dispelled by Plaintiff's summary judgment opposition brief with its robust citations to and quotes from England in defense of the supposed legality of personal drug importation.

Plaintiff's contention that England's legal conclusions should be admitted merely because the law and FDA regulations can present complex issues is unsupported by the authority it cites. *See* ECF No. 268 at 8. Plaintiff has instead cited cases where experts testify about the regulatory framework in order to provide the finder of fact with sufficient background to make a determination about liability. For example, Plaintiff cites *In re Fosamax Products Liability Litigation* to support the proposition that expert legal testimony is admissible in cases involving a complex regulatory scheme.[4] *See* ECF No. 268 at 8-9 (citing *In re Fosamax,* 645 F. Supp. 2d

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[3] Some of the out-of-circuit cases Plaintiff cites do not reflect Second Circuit law.

[4] As explained *supra* at II.A.1 the illegality of personal drug importation is clearly set forth in *Canadian Import*, and cannot be contested by pointing to a law (21 U.S.C. § 384(j)) that is

164, 191, 209 (S.D.N.Y. 2009). But, in *Fosamax*, one expert's testimony about "the complex regulatory framework that inform[ed] the standard of care" was admitted to assist the finder of fact in determining whether the defendant complied with the pertinent standard of care. 645 F. Supp. 2d at 191. In fact, to the extent her testimony was "too conclusory," it was not admissible. *Id.*[5] Similarly, in *In re Namenda Direct Purchaser Antitrust Litigation*, expert regulatory testimony was admitted that "simply explain[ed] the mechanics of drug approval" to "provide[] context," and which did not provide legal conclusions or opine on whether there were violations of the law. 331 F. Supp. 3d 152, 184 (S.D.N.Y. 2018).

Plaintiff's other authorities relate to expert legal opinions that were similarly attenuated from the central issue in the case. *See Am. Home Assurance Co. v. Merck & Co.*, 462 F. Supp. 2d 435, 448, 453 (S.D.N.Y. 2006) (admitting expert regulatory testimony to help determine the reasonableness of the defendant's interpretation of the regulatory scheme to assist in deciding liability under an insurance contract, while excluding expert testimony interpreting the contract because it "imping[ed] upon the province of the Court"); *Wisconsin v. Indivior Inc. (In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.)*, No. 13-MD-2445, 2020 U.S. Dist. LEXIS 219949, at *135, *148-50 (E.D. Pa. Nov. 24, 2020) (admitting expert regulatory testimony to help the finder of fact understand whether the defendant's safety

not effective and a policy statement. Thus, this case is not one where background information would be useful to the trier of fact.

[5] The second and third regulatory experts were allowed to testify because the defendant moved to exclude their testimony on general causation but the plaintiff agreed that the experts would not offer an opinion on general causation, rendering the motion to exclude their testimony moot. *Fosamax*, 645 F. Supp. 2d at 201. With respect to Plaintiff's cited contention that "competing expert testimony and cross-examination will allow the jury to carefully weigh such testimony," ECF No. 268 at 9, the court was referring to dueling interpretations of epidemiological data, not the law. *See id.* at 209.

statements were false and misleading while excluding "a legal opinion that usurps the jury's role in applying the law to the facts"); *Utica Mut. Ins. Co. v. Munich Reinsurance Am., Inc.*, No. 6:12-cv-00196 (BKS/ATB), 2018 U.S. Dist. LEXIS 106970, at *18-19 (N.D.N.Y. June 27, 2018) (admitting expert testimony to provide background on insurance industry practices); *Drake v. Allergan, Inc.*, No. 2:13-cv-234, 2014 U.S. Dist. LEXIS 151830, at *15 (D. Vt. Oct. 23, 2014) (admitting expert regulatory testimony to assist in assessing the requisite standard of care, but excluding "testimony about legal definitions" and whether the defendants complied with regulations); *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 447-48 (E.D.N.Y. 2011) (admitting expert regulatory testimony, while excluding legal conclusions); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2011 U.S. Dist. LEXIS 145593, at *37-8 (S.D. Ill. Dec. 16, 2011) (admitting expert regulatory testimony to help the finder of fact determine how regulations inform the requisite standard of care).

Indeed, in *Krys v. Aaron*, a case cited in Plaintiff's Opposition, the parties acknowledged that their experts were "preclude[d] . . . from testifying on questions of law or from stating ultimate conclusions of law[.]" 112 F. Supp. 3d 181, 190 (D.N.J. 2015). The trial court excluded expert regulatory opinions concerning the defendants' compliance with their obligations under federal securities law, finding it "unquestionably invades the Court's province by rendering a legal opinion[.]" *Id.* at 192 (emphasis in original). No expert was permitted to testify on the dispositive issues in the case, because while an expert "may . . . reach an ultimate issue in a case," they "may not provide an ultimate legal opinion." *Id.* at 205-06.

England here seeks to offer legal conclusions about the legality of prescription drug importation. These are not explanatory background opinions. Plaintiff relies heavily and almost

exclusively on England's testimony about the laws governing prescription drug importation in its opposition to Defendants' summary judgment motion to establish the supposed legality of drug imports. This is impermissible because it is a question for the Court, not an expert.

B. The Court Should Exclude England's Unreliable, Speculative Opinions.

England's opinions also should be excluded because they are unreliable speculation and, moreover, irrelevant to the issues in the case. Although Plaintiff argues that England's fourth opinion is that Plaintiff "has an accreditation program with requirements that are consistent with legal importation rules[,]" ECF No. 268 at 19, what he actually opines is that Plaintiff's accreditation program requirements are "designed to ensure participating pharmacies conform to the FDA policy[.]" Ex. 3 at 5. England's fourth opinion should be excluded as unfounded speculation about the intent of Plaintiff in designing its accreditation program. Plaintiff argues that "England is not being proffered to testify as to the institutional intent of motive of plaintiff" and instead this "situation is just like the one in *Halfmoon*[.]" ECF No. 268 at 20 (citing *Town of Halfmoon v. GE*, 1:09-CV-228, 2016 U.S. Dist. LEXIS 26888 (N.D.N.Y. Mar. 3, 2016)). But the *Halfmoon* Court admitted an expert's testimony that was "based on a review of the paper trail created by" a party and "an examination of whether or not any of the documentary evidence produced in discovery substantiate[d] [its] claim[.]" *Halfmoon*, 2016 U.S. Dist. LEXIS 26888, at *46. England reviewed no such paper trail or documentary evidence—rather, he simply "evaluated the information that was available on PharmacyChecker.com[.]" Ex. 2 at 371:7-11. Plaintiff apparently concedes this point as it now describes England's opinion as based upon Plaintiff's policies "as stated on its website[.]" ECF No. 268 at 4.

Moreover, in defending England's opinion about the design of Plaintiff's accreditation program, Plaintiff also confirms that it is irrelevant to the question of whether Plaintiff facilitates

illegal importation.[6] Plaintiff admits England "is not being proffered to opine as to plaintiff's performance in implementing and enforcing its policies" nor "as to whether any one pharmacy complies with applicable regulations." ECF No. 268 at 22. His testimony does not speak to what Plaintiff or its pharmacy customers do in practice and would not help the finder of fact determine whether Plaintiff is facilitating illegal importation. Even putting aside reliability, the Court should exclude England's fourth opinion because it is irrelevant to the issues at hand.

Finally, the Court should exclude England's opinions to the extent they purport to speak to FDA enforcement discretion. Plaintiff argues that England's testimony about FDA enforcement discretion was a "tangent" Defendants "contrived" at his deposition and that "officer discretion is not a basis for his opinions." ECF No. 268 at 23. Not so. In his first opinion, England opines that "FDA lacks the power to prevent such importations." Ex. 3 at 5. And in his third opinion, England opines that the PIP governs "when FDA would permit the importation of drugs that might otherwise be refused admission." *Id.* Both opinions thus rely on the FDA's enforcement of the laws governing prescription drug importation. Moreover, this testimony should be excluded as irrelevant and unhelpful to the trier of fact because the ways the FDA chooses to enforce the law do not speak to the legality of importation.

III. CONCLUSION

For the foregoing reasons, as well as those stated in their opening brief, Defendants respectfully request the Court exclude the expert testimony of Benjamin England, Esq. in its entirety.

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[6] Plaintiff's statement that "defendants are conceding that plaintiff is not acting illegally and [is] not involved in prescription drug transactions[,]" ECF No. 268 at 19-20, is directly contradicted by Defendants' argument in its opening brief that "PCC actively intervenes on behalf of U.S. consumers attempting to buy prescription drugs from foreign online pharmacies." ECF No. 262 at 18.

DATED: August 5, 2022

Respectfully submitted,

/s/ Erik T. Koons
Erik T. Koons (*Pro Hac Vice*)
Jana I. Seidl (*Pro Hac Vice*)
BAKER BOTTS L.L.P.
700 K St. NW
Washington, DC 20001
Telephone: (202) 639-7973
Facsimile: (202) 585-1086
erik.koons@bakerbotts.com
jana.seidl@bakerbotts.com

Counsel for Defendant National Association of Boards of Pharmacy

/s/ Leslie E. John
Leslie E. John (*Pro Hac Vice*)
john@ballardspahr.com
Elizabeth P. Weissert (*Pro Hac Vice*)
weisserte@ballardspahr.com
BALLARD SPAHR LLP
1735 Market Street, 51st Floor
Philadelphia, PA 19103
Phone: 215-665-8500

Justin W. Lamson (ID. 770895)
lamsonjw@ballardspahr.com
BALLARD SPAHR LLP
1675 Broadway, 19th Floor
New York, New York 10019
Telephone: (212) 223-0200

Counsel for Defendant Partnership for Safe Medicines, Inc.

/s/ Rachel J. Adcox
Rachel J. Adcox (*Pro Hac Vice*)
Melanie Kiser (*Pro Hac Vice*)
AXINN VELTROP & HARKRIDER LLP
1901 L St NW
Washington, DC 20036
Tel: 202-912-4700
Fax: 202-912-4701
radcox@axinn.com
mkiser@axinn.com

Denise Plunkett
AXINN VELTROP & HARKRIDER LLP
114 West 47th Street
New York, NY 10036
Tel: 212-728-2200
Fax: 212-728-2201
dplunkett@axinn.com

Counsel for Defendant Alliance for Safe Online Pharmacies

/s/ Barry Werbin
Barry Werbin, Esq.
Nicholas Grant Olear Veliky, Esq.
HERRICK, FEINSTEIN LLP
Two Park Avenue
New York, New York 10016
Tel.: 212-592-1418
bwerbin@herrick.com
nveliky@herrick.com

Counsel for Defendant Center for Safe Internet Pharmacies Ltd.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, on this 5th day of August, 2022, I caused the foregoing Reply Memorandum of Law in Support of Defendants' Joint Motion to Exclude the Expert Testimony of Benjamin England, Esq. to be served via email on all counsel of record in accordance with the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the Southern District of New York.

/s/ *Leslie E. John*
Leslie E. John